European Medicines Agency
Press office

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PRESS RELEASE
Meeting highlights from the Paediatric Committee, 13-15 February 2008

Positive opinions on paediatric investigation plans adopted
The European Medicines Agency's (EMEA) Paediatric Committee (PDCO) adopted positive opinions on paediatric investigation plans for the following medicines:

- Doripenem monohydrate, from Johnson & Johnson PRD, in the therapeutic area of infectious diseases;
- Paliperidone, from Janssen Cilag International, in the therapeutic area of psychiatry;
- Docetaxel, from Aventis Pharma SA, in the therapeutic area of oncology.

A paediatric investigation plan (PIP) sets out a programme for the development of a medicine in the paediatric population. The PIP aims to generate the necessary quality, safety and efficacy data through studies to support the authorisation of the medicine for use in children of all ages. In some cases, a PIP may include a waiver of the submission of data in one or more age groups of children.

Product-specific waivers
The PDCO adopted product-specific waivers for naproxcinod[**], from NicOx S.A., in the therapeutic area of rheumatology, and fosfluridine tidoxil[*], from Heidelberg Pharma, in the therapeutic area of dermatology, recommending that the obligation to submit data obtained through clinical studies with children be waived in all subsets of the paediatric population.

Waivers can be issued if there is evidence showing that the medicinal product concerned is likely to be ineffective or unsafe in the paediatric population, or that the disease or condition targeted occurs only in adult populations, or the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

Decisions adopted
The EMEA adopted a decision on a PIP for L-Asparaginase. In addition the Agency adopted decisions on product-specific waivers in all subsets of the paediatric population for telmisartan/ramipril, rosiglitazone maleate, panobinostat, indacaterol maleate, glycopyrronium bromide and indacaterol maleate/glycopyrronium bromide. These decisions are published on the EMEA website at: http://www.emea.europa.eu/htms/human/paediatrics/decisions.htm

Requirements for PIP applications for pandemic vaccines
The PDCO started a discussion on which paediatric data would be needed for the development of flu vaccines for paediatric use. The vaccines concerned include seasonal flu vaccines, pre-pandemic vaccines and flu pandemic vaccines. This work will be performed in collaboration with the Vaccines Working Party of the Committee for Medicinal Products for Human Use (CHMP).

Other ongoing activities
The PDCO continued to review scientific and operational issues, including:

[**] corr. The name of the active substance has been corrected.

[*] corr. The information for fosfluridine tidoxil has been corrected to read that the PDCO positive opinion was adopted for a product-specific waiver.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 09
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

- Discussion on the update of the priority list for studies into off-patent medicines (not covered by a patent in Europe) in advance of the next call from the European Commission for funding through the EU's Seventh Framework Programme. Once updated, the list will be released for public consultation.
- Feedback by PDCO's working groups on paediatric formulations and on neonatal immunisation in relation to issues identified during the evaluation of PIPs and/or waiver applications.
- Interaction with experts in the area of endocrinology and neurology with a view to bringing state-of-the-art knowledge to the PDCO's scientific discussions.

The PDCO was informed of the publication by the European Commission of the Ethical Recommendations for Clinical Trials in children and the decision of the European Commission on a symbol for paediatric medicines following the recommendation made by the PDCO in January 2008 (http://www.emea.europa.eu/pdfs/human/paediatrics/49824707en.pdf).

The next meeting of the PDCO will be held on 12-14 March 2008.

-- ENDS --

Notes:

1. PDCO opinions on PIPs and waivers are transformed into EMEA decisions within the timeframe laid down by the Paediatric Regulation (Regulation (EC) No 1901/2006, as amended).
2. The priority list for studies into off-patent medicines helps to ensure that funds are directed into research of off-patent medicines, for which there is a high need in the paediatric population. Ultimately, the aim is that more of these medicines can be submitted to the EMEA for a paediatric-use marketing authorisation. The priority list for studies into off-patent medicinal products can be found at: http://www.emea.europa.eu/pdfs/human/paediatrics/19797207en.pdf
3. More information about the PDCO and the Paediatric Regulation is available on the 'Medicines for children' section of the EMEA website at: http://www.emea.europa.eu/htms/human/paediatrics/introduction.htm
4. This press release, together with other information on the work of the EMEA, can be found on the EMEA website: www.emea.europa.eu

Media enquiries only to:
Martin Harvey Allchurch or Monika Benstetter
Tel. (44-20) 74 18 84 27, E-mail press@emea.europa.eu

OVERVIEW OF PAEDIATRIC INVESTIGATION PLAN/WAIVER APPLICATIONS

Total cumulative number of validated paediatric investigation plans (PIP) / waiver applications[1] 117[2]

- Applications submitted for a product not yet authorised (Article 7)[3] 64 *(55%)*
- Applications submitted for a product already authorised still under patent in view of a submission of a variation/extension for a new indication, pharmaceutical form or route of administration (Article 8) 52 *(44%)*
- Applications submitted for an off-patent product developed specifically for children with an age-appropriate formulation (Article 30) 1 *(1%)*

PIPs and full waiver indications covered by these applications 241

Areas covered by PIPs/waivers:	**%**
Neurology	11
Uro-nephrology	-
Gastroenterology-hepatology	6
Pneumology-allergology	8
Infectious diseases	9
Cardiovascular diseases	9
Diagnostics	-
Endocrinology-gynaecology-fertility-metabolism	21
Neonatology-paediatric intensive care	-
Immunology-rheumatology-transplantation	5
Psychiatry	5
Pain	2
Haematology-haemostaseology	2
Otorhinolaryngology	-
Oncology	12
Dermatology	1
Vaccines	4
Ophthalmology	2
Anaesthesiology	1
Nutrition	2

Number of Paediatric Committee (PDCO) opinions	
On full waiver	12
On PIPs including potential deferral	9

[1] Figures including 14 February 2008 start of procedure; the figure does not include products which are currently under validation.
[2] Of which 19 are requests for full waiver in all subsets of the paediatric population.
[3] Applications submitted in accordance with Regulation (EC) No 1901/2006, as amended.